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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,339	12/19/2001	Hans-Peter Harz	50091	1787
26474	7590	06/24/2004	EXAMINER	
KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			HANLEY, SUSAN MARIE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,339

Applicant(s)

HARZ ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/19/01</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-7 and 10-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 10/125,272. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a method for preparing an enzyme-containing granulate suitable for use in animal feed wherein the granulate is coated with a polymer, polyethylene glycol having a molecular weight ranging from 4,000 to 20,000 D. Claims 1-6 of the instant application are drawn to a process for making a granulate that is coated by a polymer. Claims 7 and 11-18 of the instant application are drawn to a process, and product thereof, for making a granulate that is coated by polyethylene glycols having an average molecular weights of 1,000 to 15,000 or 400 to 15,000. The copending application claims the polymer specie, polyethylene glycol having a molecular weight of 4,000 to 20,000 D, as a granulate coating. The claims of the copending application are obvious over the instant application because the polymer specie disclosed by 10/125,272 falls within the genus of polymers (claims 1-6) and polyethylene glycols (claims 7 and 10-18) of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 24-27 of copending Application No. 10/280,324 in view of Itoh et al. (US 5,080,917).

'324 claims a method of making, and a product thereof, an enzyme-containing granulate suitable for use in an animal feed. '324 does not disclose that the granules are coated with a polymer.

Itoh et al. disclose polymer-coated granules for animal feed and a method of making said granules. The core can comprise a starch and an active substance. Itoh et al. teach that it is desirable to coat enzyme-containing granules that are suitable for animal feed because the polymer coating protects the enzyme from acidic degradation in the animals' stomach (col. 1, lines 12-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the enzyme-containing granules taught by '324 with a polymeric substance. The ordinary artisan would have been motivated to do so because such a coating serves to protect the enzyme from acidic degradation in the stomach of

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the animal. Hence, more of the enzyme would survive the first pass effect and would be available to cause the desired therapeutic effect in the animal. The ordinary artisan would have had a reasonable expectation that an enzyme-containing granule could be successfully coated by a polymer and subsequently be used as animal feed because Itoh et al. teaches that polymer-coated enzyme-containing granules are well known in the art and that their invention is merely an improvement on well known technology.

This is a provisional obviousness-type double patenting rejection.

Claim Objections

Claim 16 is objected to because of the following informalities: The term "1x10³" appears to be a number in exponential notation. It is suggested that the "3" be amended as a superscript. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the term "post-drying" is vague and indefinite. It is unclear if "post" means later in the process or has some other meaning.

The terms "coarse" and "narrow" in claims 1 and 5, respectively, are relative terms which render the claims indefinite. The terms "coarse" and "narrow" are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Regarding claims 7(a), 7 (b), 8 (a), 10 (a), 11 (a), 11 (b), and 11(g), the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 7(a), 7 (b), 8 (a), 10 (a), 11 (a), 11 (b), and 11(g) broadly recite a genus of polymers, and the claims also recites "in particular," and then names several species in the claimed genus, which is the narrower statement of the range/limitation.

Claims 8 (b) and 11 (h) are rejected because the phrase "possibly stabilized with polyvinylpyrrolidone" is vague. "Possibly" is a conditional term and it is not clear if and/or when it is appropriate to add the polymer to the claimed mixture.

Claims 12, 13 and 16 are rejected because the term "it" is vague and indefinite. It is unclear to what "it" refers.

Claim 17 is rejected because the phrase "customary constituents" is vague and indefinite. It is not clear what characteristics make some "customary." The metes and bounds of the term "constituents" are undefined.

Claims 11-16 and 18 provide for the use of a feedstuff additive, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. The claims will be treated as composition claims.

Claims 11-16 and 18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 16 is rejected because the number "1x10s" is confusing. It is unclear what the letter "s" means.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8, 11-14, 17 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Itoh et al. (US 5,080,917).

Itoh et al. disclose coated granules for animal feed and a method of making said granules, as in claims 1 and 17. The core can comprise a starch and an active substance. The active substance can be an enzyme such as a protease (col. 2, lines 44-50), as in claims 1, 13 and 14. Other constituents include amino acids and vitamins, as in claim 17. The enzyme-core granulate is prepared by conventional means which include granulating, drying and making the granule in a spherical shape (col. 4, lines 15-55), as in claims 1-4. The coating agent comprises copolymers formed from alkyl esters of methacrylic acid and dimethylaminoethyl methacrylate. The molecular weights of the copolymers are in the range of 50,000 to 500,000 (col. 3, lines 1-10), as in claims 8 and 11. Itoh et al. disclose that these polymeric coatings are water soluble and can be applied by a spraying method as an aqueous solution to the granules (col. 4, lines 55-64), as in claim 6. The polymer coating can be applied to the granule individually or with an additive such as ethyl cellulose (col. 3, lines 35-40). It is noted that the language of the instant claims is open and that the claimed coatings can comprise other substances. The ratio of the coating to the granule core is at a weight ratio of 5 parts per 100 parts core (col. 4, lines 30-40). Thus, in a coated granule, the percent weight ratio is about 2.5 to 50%, as in claims 8 and 11. The diameter of the granule is in the range of 0.5 to 3.0 mm (col. 5, lines 1-10), as in claims 5 and 12.

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Claims 1-7 and 10-18 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by De Lima et al. (US 6,136,772) in light of Markussen (US 4,106,991).

De Lima et al. disclose coated enzyme-containing granules and a method of making thereof. The product can be used for animal feed or detergent (col. 16, lines 33-49), as in claim 17 and 18. The enzyme can be a phytase, a protease, a transferase or a carbohydrase (col. 15, lines 1-68 and col. 16, lines 46-48), as in claims 13-14. The granular core particles can be prepared by conventional means including granulation, pelletization, extrudation and spheroidization (col. 10, lines 57-65), as in claims 1-4. The enzyme-starch granulate can be coated by spraying the coating material onto the surface of the granulate in a fluidized bed, as in claim 6. The coating material can be in the form of a powder. De Lima et al. teach a powdery mixture comprising PEG 4000, kaolin and titanium dioxide (col. 33, lines 56-68.) De Lima et al. teach that there can be one or more coating layers. The coating layer can comprise 0.5 to 50% by weight of the finished granule. De Lima et al. disclose that the coating can comprise polyethylene glycol, and can be utilized in the manner described by Markussen et al. (US 4,106,991; col. 11, lines 20-25). Markussen et al. teaches that PEG 1500 or PEG 6000 can be sprayed on hot granulates to form an outer coating (col. 16, lines 12-22), as in claims 7, 10 and 11. The disclosure by Markussen et al. is a supporting reference and properly used in a rejection under 35 U.S.C. 102 since it describes the use of PEG as a coating and De Lima et al. refer directly to the Markussen patent.. MPEP 2131.01.

In Example 26, De Lima et al. related that cassava cores were sprayed with a phytase solution, mixed and dried in a fluidized bed. The activity of the phytase after dilution but before combination with the starch core was 10,700 FYT/g, as in claims 15-16. The resulting granulate was coated with hydrogenated palm oil and talc. De Lima et al. disclose that other coatings are available and suitable for all enzyme/starch granulates. For example, enzyme-containing granulates can be coated with an aqueous solution of polyethylene glycol 4000 (col. 25, lines 24-26). The overall size distribution is narrow. The granulate can have a size in the range of 50-4000 μ (claim 14), as in claims 5 and 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Becker et al. (US 2002/0034549) in view of Maruyama et al. (JP 408333239 A and Machine Translation).

Becker et al. teach coatings for granules that can be used for feed compositions. The granule core comprises an enzyme and a carrier. The coating comprises a modified starch and a plasticizer. The modified starch is preferably hydroxypropyl methyl cellulose. The plasticizer is glycerol, a polyethylene glycol having a molecular weight of 200-8000, triethylcitrate and so on (p. 2, section 0019). The carrier-enzyme granulate was prepared by mixing sucrose, cornstarch and enzyme and then placing the mixture on a fluidized bed granulator (p. 3, Example 1). Pure Cote B790 (hydroxypropyl methylcellulose) was combined with water, a plasticizer and other ingredients. The resulting solution was sprayed onto the granules as an aqueous dispersion (p. 2, section 0051).

Becker et al. do not teach the application of a coating of solid hydroxypropyl methyl cellulose and a plasticizer to the granule.

Maruyama et al. disclose a method to coat a granular preparation or a bulk medicine with a fine powdery enteric coating agent such as hydroxymethyl propyl cellulose acetate succinate. The plasticizer is sprinkled on the solid coating composition in a liquid state plasticizer at room temperature. The plasticizer can be triethyl citrate. There are several advantages of a solventless enteric coating process. The solventless coating does not require drying and is completed in a short period of time. Further, it is unnecessary to add dispersing agents that are required for aqueous enteric coating processes. The powder coating process affords an enteric coating that is resistant to acid.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the enzyme granulate disclosed by Becker et al. with a coating comprising a solid polymer of hydroxymethyl propyl cellulose that is mixed with a plasticizer. Becker et al. disclose that it was known at the time of the invention that an aqueous combination of hydroxypropyl methyl cellulose and a plasticizer provide a stable film coating that is suitable for stabilizing enzyme granulates. The ordinary artisan would have been motivated to coat the enzyme granulate by the solventless powdery coating process disclosed by Maruyama et al. because said method would shorten the time required for the manufacturing process and eliminate the need for an aqueous dispersing agent. The

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ordinary artisan would have had a reasonable expectation that the solventless powdery coating process disclosed by Maruyama et al. could be applied to the enzyme granulates disclosed by Becker et al. because the process is suitable to protect granulates and medicines from harmful substances such as acids.

Claims 1-7 and 10-18 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/125,272 which has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

The copending application '272 discloses a method for preparing an enzyme-containing granulate suitable for use in animal feed wherein the granulate is coated with a polymer, polyethylene glycol having a molecular weight ranging from 4,000 to 20,000 D. The disclosure of '272 is obvious over the instant application because the polymer specie disclosed by '272 falls within the genus of polymers (claims 1-6) and polyethylene glycols (claims 7 and 10-18) of the instant application.

Claims 1-18 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/280,324 which has a common assignee with the instant application in view of Itoh et al. US 5,080,917. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

'324 discloses a method of making, and a product thereof, an enzyme-containing granulate suitable for use in an animal feed. '324 does not disclose that the granules are coated with a polymer mixture.

Itoh et al. disclose polymer-coated granules for animal feed and a method of making said granules. The core can comprise a starch and an active substance. Itoh et al. that it is desirable to coat enzyme-containing granules that are suitable for animal feed because the polymer coating protects the enzyme from degradation in the animals' stomach (col. 1, lines 12-24).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the enzyme-containing granules taught by '324 with a polymeric substance. The ordinary artisan would have been motivated to do so because such a coating serves to protect the enzyme from degradation in the acidic stomach of the animal. Hence, more of the enzyme would survive the first pass effect and would be available to cause the desired therapeutic effect in the animal. The ordinary artisan would have had a reasonable expectation that an enzyme-containing granule could be successfully coated by a polymer and subsequently be used as animal feed because Itoh et al. teaches that polymer-coated enzyme-containing granules are well known in the art and that their invention is merely an improvement on well known technology.

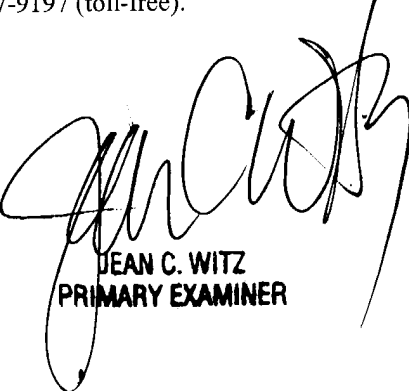
These provisional rejections might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JEAN C. WITZ
PRIMARY EXAMINER